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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,704	11/20/2003	Angela Soito	005284.00226	7077

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EXAMINER	
ROY, ANURADHA	
ART UNIT	**PAPER NUMBER**
3736	

DATE MAILED: 05/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/716,704	SOITO ET AL.	
	Examiner	Art Unit	
	Anuradha Roy	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-23 and 26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-23 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/20/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 17-23 & 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Hung et al. (US Patent No. 6,413,228).

In regards to claim 17, Hung et al. discloses a system of cytological evaluation of epithelial cells (Abstract & Column 28 line 51 – Column 29, line 14) collected from a human breast duct comprising:

- a tool (Figure 3) for accessing a breast duct and collecting breast duct fluid from a human breast while the tool is in the duct;
- a chart or written guidelines (Column 13, lines 66 – Column 14, line 12) for evaluating the ductal epithelial cells in the sample for one or more

observed indicia selected from the group consisting of cell grouping, cell shape, cell size, nuclear size, nuclear shape, presence or absence of nucleoli, nuclear-to-cytoplasmic ratio, vacuoles in the cytoplasm, cytoplasmic shape, cytoplasmic border, presence or absence of anisonucleosis, presence or absence of mitotic figures, nuclear membrane quality, presence of necrotic debris, chromatin distribution, coarseness of chromatin, and the presence or absence of microcalcifications (Column 13, lines 51-55 & Column 25, lines 6-33); and

- an algorithm (Column 12, line 56 – Column 17, line 10 & Column 26, lines 35-48) for classifying the sample as being normal, atypical or malignant based on the observed indicia.

Regarding claim 18, Hung et al. discloses a system, wherein the tool for accessing a breast duct comprises a breast duct access and fluid and cell retrieval tool, and one or more of a probe, a tool for administering anesthetic, marking tools for marking an accessed or fluid yielding duct, or a collection receptacle for collecting retrieved fluid and cells (Column 18, line 24 – Column 19, line 15).

With regard to claim 19, Hung et al. discloses a system, wherein the algorithm classifies the sample as malignant when the sample is characterized by at least an identifying feature selected from the group consisting of a loss of cell cohesiveness, loose clusters of epithelial cells, enlarged cells, enlarged nuclei, high nuclear-to-cytoplasmic ratio, increased cytoplasm in some cells, irregular nuclear membranes,

clumped chromatin, hyperchromatic chromatin, unevenly dispersed chromatin, enlarged nucleoli, multiple nucleoli, marked variation among the cells of the sample in cell size and nuclear size, necrotic debris, and microcalcifications in background material appearing as dense material with smooth borders and concentric layers or dystrophic and amorphous (Column 13, lines 51-55 & 66- Column 14, lines 12 & Column 25, lines 6-33).

In regards to claim 20, Hung et al. discloses a system, wherein the algorithm classifies the sample as atypical with marked changes when the sample is characterized by at least an identifying feature selected from the group consisting of enlarged ductal epithelial cells, marked nuclear increase in ductal epithelial cells, variation in size and shape of the ductal epithelial cells as compared to normal ductal epithelial cells, abundant cytoplasm in some cells, decreased nuclear-to-cytoplasmic ratios in some cells, coarse chromatin, mild abnormality in chromatin distribution, larger nucleoli than in normal cells, multiple nucleoli, more prominent nucleoli, groups of nuclei that appear to be overlapping, and mitotic figures (Column 13, lines 51-55 & Column 25, lines 6-33).

Regarding claim 21, Hung et al. discloses a system, wherein the algorithm classifies the sample as atypical with mild changes when the sample is characterized by at least some of an identifying feature selected from the group consisting of single ductal cells, cohesive multilayered cells, complex groups of cells, monolayered cells, an increased number of cell layers compared to normal cells, increased overlapping of the cells, nuclear crowding of cells, minimally enlarged cells, moderate increase in nuclear

size to within a range from about 12 to about 16 μm in diameter, slight anisonucleosis in some cells, and presence of nucleoli (Column 13, lines 51-55 & 66- Column 14, lines 12 & Column 25, lines 6-33).

In regards to claim 22, Hung et al. discloses a system, wherein the algorithm classifies the sample as normal when the sample is characterized by at least some of an identifying feature selected from the group consisting of single cells, monolayer sheets, tight cells clusters having a thickness of one or two cell layers, small nuclei in a size range from about 8 to about 12 μm in diameter, high nuclear-to-cytoplasmic ratio depending on the orientation of the cells in clusters, in single cells a columnar shape of cytoplasm, in single cells discreet small vacuoles in the cytoplasm, in single cells discreet cytoplasmic border, cohesive groups of ductal epithelial cells with cells of uniform size and regular round to oval shape, monolayer sheets of cells with uniform, small cells, and monolayer sheets of cells with small inconspicuous nucleoli (Column 13, line 5 – Column 14, line 51 & Column 25, lines 6-33).

Regarding claim 23, Hung discloses a system, wherein the algorithm inherently classifies the sample as insufficient cells to make a diagnosis when the sample has fewer than 10 epithelial cells (Column 33, lines 28-30).

Regarding claim 26, Hung et al. discloses a system of cytological evaluation of epithelial cells (Abstract & Column 28 line 51 – Column 29, line 14) collected from a human breast duct comprising:

- a tool (Figure 3) for accessing a breast duct and collecting breast duct fluid from within the breast duct, said tool comprising an elongated portion shaped and sized for extending into the breast duct comprising a single elongated internal lumen through which fluid can be introduced and retrieved from within the breast duct (Column 18, line 24 – Column 19, line 15);

- a chart or written guidelines for evaluating the ductal epithelial cells in the sample for one or more observed indicia selected from the group consisting of cell grouping, cell shape, cell size, nuclear size, nuclear shape, presence or absence of nucleoli, nuclear-to-cytoplasmic ratio, vacuoles in the cytoplasm, cytoplasmic shape, cytoplasmic border, presence or absence of anisonucleosis, presence or absence of mitotic figures, nuclear membrane quality, presence of necrotic debris, chromatin distribution, coarseness of chromatin, and the presence or absence of microcalcifications (Column 13, lines 51-55 & Column 25, lines 6-33); and

- an algorithm (Column 12, line 56 – Column 17, line 10 & Column 26, lines 35-48) for classifying the sample as being normal, atypical or malignant based on the observed indicia.

Conclusion

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Anuradha Roy whose telephone number is (571) 272-6169 and whose email address is anuradha.roy@uspto.gov. The examiner can normally be reached between 8:00am and 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

~AR~

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